UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JEANNIE PATORA and NANCY KANE, individually on behalf of themselves and all others similarly situated, Plaintiffs,	**OPINION AND ORDER**
v.	22 CV 6678 (VB)
VI-JON, LLC, Defendant.	

Briccetti, J.:

Plaintiffs Jeannie Patora and Nancy Kane bring this consolidated putative class action against defendant Vi-Jon, LLC, arising out of defendant's allegedly deceptive labeling of certain laxative products purportedly contaminated with a bacterium not listed as an ingredient or mentioned on the products' labeling.

Plaintiffs assert claims for deceptive acts or practices and false advertising under New York General Business Law ("GBL") Sections 349 and 350, seeking various forms of economic damages and equitable relief.[1]

Now pending is defendant's motion to dismiss the consolidated amended complaint ("CAC") under Rule 12(b)(6). (Doc. #17).

For the following reasons, the motion is GRANTED.

The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d).

BACKGROUND

For the purpose of ruling on the motion to dismiss, the Court accepts as true all well-pleaded allegations in the CAC, as well as in documents incorporated by reference in or

[1] Plaintiffs voluntarily withdrew their breach of express warranty claims pursuant to various other states' laws. (Doc. #19 ("Pls. Opp.") at 2 n.2).

documents integral to the CAC, and draws all reasonable inferences in plaintiffs' favor, as summarized below.

Defendant—a Delaware company with its principal place of business in Missouri—manufactures magnesium citrate saline laxative products (the "Products"), which are sold under private label by various retailers throughout New York and the United States, including CVS, Rite Aid, Walgreens, Walmart, Target, Kroger, and Publix, among others.

On June 21, 2022, defendant voluntarily recalled one lot of the Products, after testing identified that the affected lot contained the bacterium Gluconacetobacter liquefaciens. (Doc. #16 ("CAC") ¶¶ 33 n.13). Soon thereafter, defendant expanded the nationwide recall to include other lots of the Products for the same risk of microbial contamination. (Id. ¶ 36 n.16).[2]

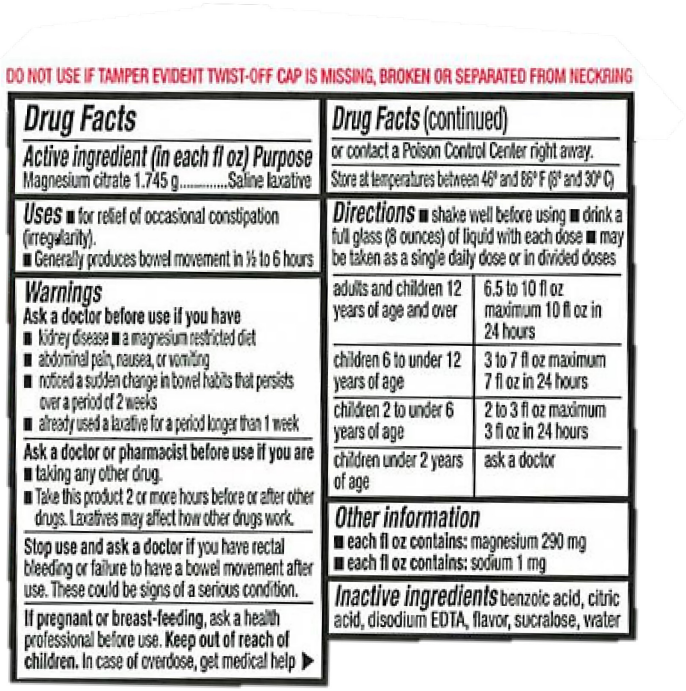
Plaintiffs allege "Gluconacetobacter liquefaciens is a gram-negative bacterium" that "can enter the manufacturing process . . . in several ways." (CAC ¶¶ 28–29). Further, ingesting Gluconacetobacter liquefaciens allegedly "can cause death to immunocompromised individuals" (id. ¶ 30), which makes "recent testing revealing" its presence in the Products "particularly concerning." (Id. ¶ 32). In addition, according to the press releases related to the recall and the consolodated amended complaint, immunocompromised consumers who use the recalled Products may be at increased risk for infections caused by Gluconacetobacter liquefaciens. (Id. ¶ 3 & n.3, ¶ 6 & n.4).

Plaintiffs, both New York residents, allege consumers "trust manufacturers such as [d]efendant to sell products that are safe and free from harmful known substances," such as

[2] Plaintiffs cite to press releases regarding defendant's various recalls of the Products because of Gluconacetobacter liquefaciens contamination in their factual allegations in the CAC. Accordingly, the Court has considered the press releases incorporated by reference in the CAC in ruling on defendant's motion. See DiFolco v. MSNBC Cable L.L.C., 622 F.3d 104, 111 (2d Cir. 2010).

Gluconacetobacter liquefaciens. (CAC ¶ 7). Plaintiffs contend they purchased and ingested defendant's over-the-counter ("OTC") Products in New York during the recall and "became ill" afterwards. (Id. ¶¶ 59, 60). Further, plaintiffs allege the Products do not list Gluconacetobacter liquefaciens as an ingredient, nor do they warn of the possibility of Gluconacetobacter liquefaciens contamination. Although the Products are sold under various brands, a representative example of the labeling is reproduced here:[3]

[3] In connection with their motion, defendant submits various example labels of defendant's Products. See Docs. ##17-6, 17-7, 17-9. Plaintiffs' CAC includes pictures of several of the Products' labels. (CAC ¶¶ 5, 12). Further, the CAC refers to and heavily relies on the content of the Products' labels in the CAC's factual allegations. Accordingly, the Court has considered the labels submitted by defendants and their contents as integral to the CAC in ruling on defendant's motions. See DiFolco v. MSNBC Cable L.L.C., 622 F.3d 104, 111 (2d Cir. 2010).



DO NOT USE IF TAMPER EVIDENT TWIST-OFF CAP IS MISSING, BROKEN OR SEPARATED FROM NECKRING

Drug Facts

Active ingredient (in each fl oz) Purpose
Magnesium citrate 1.745 g.....Saline laxative

Uses ■ for relief of occasional constipation (irregularity). ■ Generally produces bowel movement in ½ to 6 hours

Warnings

Ask a doctor before use if you have
- kidney disease ■ a magnesium restricted diet
- abdominal pain, nausea, or vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks
- already used a laxative for a period longer than 1 week

Ask a doctor or pharmacist before use if you are
- taking any other drug.
- Take this product 2 or more hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use and ask a doctor if you have rectal bleeding or failure to have a bowel movement after use. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help ▶

Drug Facts (continued)

or contact a Poison Control Center right away.

Store at temperatures between 40° and 86° F (5° and 30° C)

Directions ■ shake well before using ■ drink a full glass (8 ounces) of liquid with each dose ■ may be taken as a single daily dose or in divided doses

adults and children 12 years of age and over	6.5 to 10 fl oz maximum 10 fl oz in 24 hours
children 6 to under 12 years of age	3 to 7 fl oz maximum 7 fl oz in 24 hours
children 2 to under 6 years of age	2 to 3 fl oz maximum 3 fl oz in 24 hours
children under 2 years of age	ask a doctor

Other information
- **each fl oz contains:** magnesium 290 mg
- **each fl oz contains:** sodium 1 mg

Inactive ingredients benzoic acid, citric acid, disodium EDTA, flavor, sucralose, water

(CAC ¶¶ 5, 12).

According to plaintiffs, had they known the Products contained, or were at risk of containing, a harmful bacteria, they would not have bought the Products.

Thus, plaintiffs contend defendant deceptively marketed and falsely advertised the Products because the packaging or labeling does not mention Gluconacetobacter liquefaciens or warn consumers of the risks associated with this bacteria. They further allege the Products were "worthless" due to the purported presence of a contaminant. (CAC ¶ 61).

DISCUSSION

I. Standard of Review

In deciding a Rule 12(b)(6) motion, the Court evaluates the sufficiency of the complaint under the "two-pronged approach" articulated by the Supreme Court in Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009).[4] First, a plaintiff's legal conclusions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are not entitled to the assumption of truth and thus are not sufficient to withstand a motion to dismiss. Id. at 678; Hayden v. Paterson, 594 F.3d 150, 161 (2d Cir. 2010). Second, "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Ashcroft v. Iqbal, 556 U.S. at 679.

To survive a Rule 12(b)(6) motion, the complaint's allegations must meet a standard of "plausibility." Ashcroft v. Iqbal, 556 U.S. at 678; Bell Atl. Corp. v. Twombly, 550 U.S. 544, 564 (2007). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. at 678. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." Id. (quoting Bell Atl. Corp. v. Twombly, 550 U.S. at 556).

"In considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), a district court may consider the facts alleged in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint." DiFolco v. MSNBC Cable L.L.C., 622 F.3d 104, 111 (2d Cir. 2010). "Where a document is

[4] Unless otherwise indicated, case quotations omit all internal citations, quotation marks, footnotes, and alterations.

not incorporated by reference, the court may nevertheless consider it where the complaint relies heavily upon its terms and effect, thereby rendering the document integral to the complaint." Id.

II. Federal Preemption

Defendant argues plaintiffs' claims are expressly preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq.

The Court agrees.

A. Legal Standard

"A fundamental principle of the Constitution is that Congress has the power to preempt state law." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000). Thus, "[w]here state and federal law directly conflict, state law must give way." PLIVA, Inc. v. Mensing, 564 U.S. 604, 617 (2011). In determining whether federal preemption applies, "[c]ourts must 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act.'" Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 660 (S.D.N.Y. 2017) (quoting Wyeth v. Levine, 555 U.S. 555, 565 (2009)), aff'd sub. nom., Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699 (2d Cir. 2019).

"Express preemption is present when Congress's intent to preempt state law is explicitly stated in the statute's language." In re PepsiCo., Inc., Bottled Water Mktg. & Sales Pracs. Litig., 588 F. Supp. 2d 527, 530 (S.D.N.Y. 2008). To determine whether Congress intended to preempt state law, courts consider whether "the statute contains an express pre-emption clause." CSX Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993).

B. FDCA Preemption

Congress passed the FDCA "in 1938 as part of a comprehensive federal regulatory scheme to protect consumers from fraud or misrepresentation in the sale of food, drugs, and

cosmetics." Critcher v. L'Oreal USA, Inc., 2019 WL 3066394, at *2 (S.D.N.Y. July 11, 2019), aff'd, 959 F.3d 31 (2d Cir. 2020). "In doing so, Congress intended to create a national and uniform regulatory scheme, . . . which up until the FDCA's passage, had been subject to the disparate laws of the states." Young v. L'Oreal, Inc., 2021 WL 2295625, at *2 (S.D.N.Y. May 20, 2021), report and recommendation adopted sub nom., Young v. L'Oreal USA, Inc., 2021 WL 2292341 (S.D.N.Y. June 4, 2021); see also Goldstein v. Walmart, Inc., 2022 WL 16540837, at *5–7 (S.D.N.Y. Oct. 28, 2022).

Under the FDCA, the U.S. Food and Drug Administration ("FDA") regulates the sale of OTC drugs in the United States, including laxatives. 21 U.S.C. § 301 et seq; 21 C.F.R. § 201.307. The FDCA sets forth comprehensive requirements for labeling OTC magnesium citrate saline laxatives, including specifying the Products' ingredients and warnings. See 21 C.F.R. § 201.66; Laxative Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, 50 Fed. Reg. 2124, 2153, 2154–55 (Jan. 15, 1985).

Moreover, the FDA promulgates a "monograph," which is "a detailed regulation . . . for each therapeutic class of OTC drug products," after a notice-and-comment process. See Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin., 710 F.3d 71, 75 (2d Cir. 2013). By following a monograph, manufacturers seeking to sell a new OTC drug in interstate commerce may qualify for an FDA determination that a medication is generally recognized as safe and effective ("GRASE") while bypassing individualized review. Id. Monographs set "the FDA-approved active ingredients for a given therapeutic class of OTC drugs and provide[] the conditions under which each active ingredient is" GRASE. Id.

Congress enacted Section 505(g) of the FDCA through the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), effective March 27, 2020—allowing the FDA to issue

and revise monographs governing laxatives. CARES Act § 3854, Pub. L. No. 116–136, 134 Stat. 281 (2020). On May 2, 2023, the FDA published the monograph applicable to laxatives, including defendant's Products. FDA, Over-the-Counter Monograph M007: Laxative Drug Products for Over the-Counter Human Use (2023), available at https://dps.fda.gov/omuf/monographsearch/monograph_m007 (the "2023 Monograph"). The 2023 Monograph regulates laxative products' active ingredients and the contents of their labels. See 2023 Monograph §§ M007.16, M007.58.

The FDCA contains an express preemption provision for conflicting state laws governing OTC drugs, including laxatives; it prohibits states from establishing any requirement related to the regulation of an OTC drug "that is different from or in addition to, or that is otherwise not identical to" a requirement under the FDCA. 21 U.S.C. § 379r(a); Critcher v. L'Oreal USA, Inc., 959 F.3d at 35 (considering preemption in the similar context of cosmetics and observing that "to ensure . . . various federal requirements are not obstructed by state law . . . Congress added to the FDCA an expansive preemption provision"). Indeed,

> the FDCA preempts not only those state laws that are in conflict with it (i.e., any law that is "different from" the FDCA), but also any state law that provides for . . . requirements that are not exactly the same as those set forth in the FDCA and its regulations (i.e., any law that is "in addition to" the FDCA).

Id. at 35–36; see also Canale v. Colgate-Palmolive Co., 258 F. Supp. 3d 312, 320 (S.D.N.Y. 2017) ("Where federal law specifically regulates the subject matter of a plaintiff's state law claims, and those claims seek to impose requirements not identical to federal requirements, those state law claims are preempted.").

"[T]he term 'requirements' . . . reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." Bates v. Dow Agroscis. LLC, 544 U.S. 431, 443 (2005). A common law rule that "requires that manufacturers label or package their products in

[a] particular way" qualifies as a requirement with respect to labeling. Id. at 444.

"A state law that applies to drugs is preempted if it imposes a requirement that is not identical to the requirements of the FDCA and the FDA's regulations. But this comes with a caveat: preemption does not preclude a state-law claim if the state requirement is outside the scope of the relevant federal requirements." Bischoff v. Albertsons Cos., 2023 WL 4187494, at *2–3 (S.D.N.Y. June 26, 2023).

C. Analysis

The Court is persuaded by defendant's argument that plaintiffs' claims are expressly preempted by the FDCA labeling requirements for laxatives, as they arise from the omission of Gluconacetobacter liquefaciens from the Products' ingredients list and the absence of a warning label on the Products regarding the potential risk of bacterial infection.

First, plaintiffs' claims are expressly preempted by FDCA labeling requirements for laxatives, to the extent they result from the Products' omission of Gluconacetobacter liquefaciens in the ingredients list.

Plaintiffs' claims are premised on the allegation that the Products were purportedly contaminated with a bacteria that was not disclosed in the Products' ingredient list, despite the fact that defendant "specifically lists both the active and inactive ingredients of the Products on the labeling." (CAC ¶ 4). Even accepting this allegation as true, plaintiff does not allege the bacteria is properly considered an "ingredient" mandating its inclusion on the Products' ingredients list.

The FDA promulgated general labeling requirements for all OTC drugs, including laxatives, under which manufacturers must disclose an OTC drug's active and inactive ingredients. 21 C.F.R. § 201.66(c). The FDCA defines "active ingredient" as:

> any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

Id. § 201.66(b)(2). It further defines an "inactive ingredient" as "any component other than an active ingredient." Id. § 201.66(b)(8). A "component" is "any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product." Id. § 210.3(3) (emphasis added). The 2023 Monograph laxative-specific requirements related to ingredients do not mandate the potential inclusion of any bacteria. See 2023 Monograph § M007.16.

Here, plaintiffs do not allege defendant manufactured these products to contain Gluconacetobacter liquefaciens. Thus, Gluconacetobacter liquefaciens is not an active or inactive ingredient in these products, as those terms are defined under the FDCA, and federal law does not require it to appear on the Products' ingredients list.

Second, plaintiffs' claims are expressly preempted by the FDCA labeling requirements for laxatives, to the extent they arise from the lack of a warning label regarding the presence—or potential presence—of Gluconacetobacter liquefaciens in the Products.

The FDA enacted warning-label requirements for OTC products, including laxatives. See 21 C.F.R. § 201.66(c)(5). In addition, OTC product labels are required to contain "[a]ny required warnings in an applicable OTC drug monograph." Id. § 201.66(c)(5)(viii). The 2023 Monograph sets forth nine specific warnings that must be included on laxatives. See 2023 Monograph § M007.58.

Plaintiffs allege there is no "warning about the inclusion (or even potential inclusion)" of the bacteria in the Products, which "leads reasonable consumers to believe the Products do not

contain and are not at risk of containing dangerous chemicals like" the bacteria. (CAC ¶ 26). However, neither the general OTC requirements for warning labels nor the 2023 Monograph laxative-specific requirements for warning labels mandate a warning related to the potential inclusion of any bacteria—let alone Gluconacetobacter liquefaciens in particular. Thus, federal law does not require a warning label regarding the potential inclusion of the bacteria purportedly found in the Products.

Because the Court concludes the FDCA does not mandate disclosure of (i) Gluconacetobacter liquefaciens as a contaminant in the Products' ingredients list or (ii) the fact that Gluconacetobacter liquefaciens may possibly be included as a warning label on the Products, the duties plaintiffs seek to impose are additional to those imposed by the FDCA. See Critcher v. L'Oreal USA, Inc., 959 F.3d at 37. Plaintiffs' claims are "exactly what the FDCA does not permit." Id. Permitting such claims to move forward "would lead precisely to the patchwork of inconsistent packaging regulations that Congress sought to prevent." Goldstein v. Walmart, Inc., 2022 WL 16540837, at *12 (noting that if individuals believe the FDA has reached an incorrect conclusion, they can engage in a citizen petition).

Accordingly, plaintiffs' claims must be dismissed.[5]

[5] In their opposition brief, plaintiffs seek leave to file a second amended complaint in the event the Court grants the motion to dismiss. Since plaintiffs' claims are expressly preempted by the FDCA, repleading would be futile, and thus the application is denied. See F5 Capital v. Pappas, 856 F.3d 61, 89–90 (2d Cir. 2017). Moreover, plaintiffs filed the CAC after defendant initially moved to dismiss. Because the preemption argument was fully briefed in that motion (Doc. #10), plaintiffs were fully on notice of the preemption issue at the time they filed the CAC, and yet the CAC did not address the deficiencies made apparent by that fully briefed argument. And plaintiffs have not proffered any facts at all on the subjects on which they would replead. It is too late to do so now.

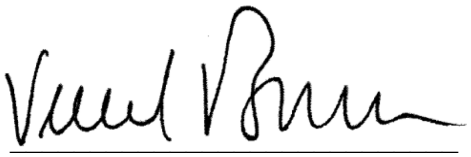
CONCLUSION

The motion to dismiss is GRANTED.

The Clerk is instructed terminate the motion (Doc. #17) and close these consolidated cases (22-cv-6678 and 22-cv-7061).

Dated: August 30, 2023
White Plains, NY

SO ORDERED:



Vincent L. Briccetti
United States District Judge